K080581

OCT 1 6 2008

Attachment 5

510(k) Summary

510(k) SUMMARY

Virtual Bronchoscopy Image Viewer

1 General Information

- Applicant:

  OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent:

  Laura Storms-Tyler
  Vice President
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-5688
  FAX: 484-896-7128
  Email:Laura.storms-tyler@olympus.com
  Establishment Registration No: 2429304

- Manufacturer:

  OLYMPUS MEDICAL SYSTEMS CORP.
  34-3 Hirai, Hinode-machi Nishitama-gun
  Tokyo, Japan 190-0182
  Establishment Registration Number: 3003637092

2 Device Identification

- Device Trade Name: VB Image Viewer
- Common Name: Virtual Bronchoscopy Image Viewer
- Regulation Number: 21 CFR 892.1750/ 21 CFR 874.4680
- Regulation Name: Computed tomography x-ray system
  Bronchoscope (flexible or rigid) and accessories
- Regulatory Class: II
- Classification Panel: Bronchoscope accessory
- Product Code: JAK

3 Predicate Device Information

- Device Name: superDimension/Bronchus
- Common Name: Computed tomography
- Manufacturer: superDimension Ltd.
- 510(k) No. K042438

4 Device Description

VB Image Viewer (Virtual Bronchoscopy Image Viewer) is the Windows software to extract the bronchus from the CT data, create 3D virtual bronchoscopy image along the route to the target position, and display the image on the PC monitor as a reference image.

Refer to Software Description for the detailed functions of VB Image Viewer, and Comparison Table for the difference between VB Image Viewer and Predicate Device.

5 Indications for Use

This instrument has been designed to display virtual bronchoscopy images to be referenced by physicians to aid guiding endoscopic tools in the pulmonary tract. It does not make a diagnosis and is not an endoscopic tool.

6 Comparison of Technological Characteristics

The Virtual Bronchoscope Image Viewer is basically identical to the predicate device in intended use, and similar in specifications except for the deletion of Extended Working Channel/ Locatable Guide/ Location Board. Comparison between the subject and predicate devices is shown in Table 1. The clinical literatures provided in this submission supports the safety and efficacy of Virtual Bronchoscopy Imaging Viewer.

Table 1. Comparison of Specifications
Subject Device: Virtual Bronchoscope Imaging Viewer
Predicate Device: superDimension/Bronchus (K042438)

Specifications	Subject Device Virtual Bronchoscope Imaging Viewer	Predicate Device superDimension/Bronchus
Software	Provided	Installed
System Controller	Recommended PC	Provided
Monitor	Recommended Monitor	Provided
Extended Working Channel	None	Provided
Locatable Guide	None	Provided
Location Board	None	Provided
Standard Set	CD-ROM	Bronchoscope
Patient Contact Materials	None	Extended Working Channel, Locatable Guide

7 Conclusion

When compared to the predicate device, the Virtual Bronchoscope Image Viewer does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2008

Ms. Laura Storms-Tyler
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K080581
Trade/Device Name: VB Image Viewer (Virtual Bronchoscopy Image Viewer)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 27, 2008
Received: October 8, 2008

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

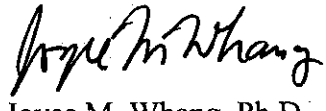
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~None~~ K080581

Device Name: VB Image Viewer (Virtual Bronchoscopy Image Viewer)

Indications For Use:

This instrument has been designed to display virtual bronchoscopy images to be referenced by physicians as an aid to guiding endoscopic tools in the pulmonary tract. It does not make a diagnosis and is not an endoscopic tool.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080581